UNITED STATES DISTRICT COURT EASTERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA, STATE OF NEW JERSEY, STATE OF NEW YORK, and STATE OF CONNECTICUT,

Civil Action No. 17-CV-2732

STATE OF CONNECTICUT,

Hon. Nicholas G. Garaufis, S.U.S.D.J. Hon. James R. Cho, U.S.M.J.

ex rel. MICHAEL WALDMAN,

LABORATORIES, INC.,

VS.

N . 4.66(T) 1 4

Plaintiff/Relator,

JURY TRIAL DEMANDED

SPECTRA HOLDCO, LLC f/k/a SHIEL HOLDINGS LLC and SPECTRA

Defendants.

DEFENDANTS SPECTRA HOLDCO, LLC F/K/A SHIEL HOLDINGS LLC AND SPECTRA LABORATORIES, INC.'S ANSWER AND AFFIRMATIVE DEFENSES TO PLAINTIFF'S THIRD AMENDED COMPLAINT AND DEMAND FOR JURY TRIAL

Come now Defendants Spectra Holdco, LLC f/k/a Shiel Holdings LLC and Spectra Laboratories, Inc., (collectively, "Defendants") and for their answer to Plaintiff's Third Amended Complaint (ECF 38) state as follows:

Unless hereinafter specifically admitted, Defendants deny each and every allegation of the Third Amended Complaint, and further deny that Plaintiff is entitled to the relief sought therein. Defendants further respectfully submit that the headings, sub-headings, footnotes, and any unnumbered paragraphs in the Third Amended Complaint do not require a response but, for the avoidance of doubt, such allegations are denied. Defendants otherwise respond to the allegations of the Third Amended Complaint as follows:

I. RESPONSE TO "INTRODUCTION"

1. Defendants admit that Plaintiff initially purported to assert qui tam claims against

Defendants on behalf of the United States, New Jersey, New York, and Connecticut in this lawsuit but deny that there was any factual or legal basis for those claims and state that the qui tam claims have been dismissed and are no longer at issue. The remaining allegations attempt to state legal conclusions to which no response is required. To the extent a response is required, Defendants deny the remaining allegations.

- 2. Defendants admit that Plaintiff purports to assert a claim under 31 U.S.C. § 3730(h) but deny that there is any factual or legal basis for his claims. Any remaining allegations are denied.
- 3. Defendants admit that the United States, New Jersey, New York, and Connecticut declined to intervene in Plaintiff's qui tam claims and the claims asserted in *U.S. ex rel. YNKDY-2 v. Shiel Medical Laboratory, et al.*, EDNY Case No. 16-1090, and that the complaints in both cases have been unsealed. To the extent paragraph 3 attempts to describe pleadings in those cases, the pleadings speak for themselves and Defendants deny any allegations inconsistent therewith. Any remaining allegations are denied.
- 4. Defendants admit that Plaintiff's qui tam claims have been dismissed and that the claim Plaintiff now asserts is limited to a single count under 31 U.S.C. § 3730(h). To the extent paragraph 4 attempts to describe pleadings, the pleadings speak for themselves, and Defendants deny any allegations inconsistent therewith. Any remaining allegations are denied.

II. RESPONSE TO "SUMMARY OF ALLEGATIONS"

5. Defendants admit that Plaintiff worked at Shiel Medical Laboratory ("Shiel"), which was owned or operated by Defendants for a period of time between approximately November 2013 through December 2017. Defendants further admit that Shiel was a clinical laboratory with locations in New York and New Jersey at the time of Plaintiff's employment. Defendants further admit that Plaintiff purports to bring this lawsuit under 31 U.S.C. § 3730(h)

but deny that there is any factual or legal basis for his claims. Defendants deny any remaining allegations.

- 6. The allegations of paragraph 6 attempt to describe or summarize Medicare and Medicaid statutes and regulations which speak for themselves, and Defendants deny any allegations inconsistent therewith. To the extent that the allegations attempt to state legal conclusions, no response is required. Defendants deny any remaining allegations.
- 7. The allegations of paragraph 7 attempt to describe or summarize Medicare and Medicaid statutes and regulations which speak for themselves, and Defendants deny any allegations inconsistent therewith. To the extent that the allegations attempt to state legal conclusions, no response is required. Defendants deny any remaining allegations.
 - 8. Denied.
 - 9. Denied.
- 10. Defendants admit that "Missing Diagnosis Codes" or "Missing ICD9" sheets were used from time to time in connection with collecting diagnosis codes and admit that Shiel required diagnosis codes to be received from the ordering physician or other authorized person. Defendants deny that paragraph 10 fully and accurately reflects Shiel's practices. The remaining allegations are denied.
- 11. The allegations of paragraph 11 attempt to describe or summarize Medicare regulations and internal documents that speak for themselves, and Defendants deny any allegations inconsistent therewith. To the extent that the allegations attempt to state legal conclusions, no response is required. Defendants deny any remaining allegations.
 - 12. Denied.
 - 13. Defendants admit that commissions were a part of the compensation potentially

available to Shiel sales representatives. Defendants deny the remaining allegations.

- 14. Denied.
- 15. Denied.
- 16. Denied.
- 17. Denied.
- 18. Denied.
- 19. Denied.
- 20. Defendants admit that Plaintiff's employment was terminated in connection with the sale of Shiel to another laboratory company in 2017. Defendants deny the remaining allegations.

III. RESPONSE TO "JURISDICTION, VENUE, AND SPECIAL REQUIREMENTS"

- 21. Defendants admit that Plaintiff purports to invoke jurisdiction under 28 U.S.C. § 1331 and 31 U.S.C. § 3729. Defendants state that any purported qui tam claims under 31 U.S.C. § 3729 have been dismissed. Defendants deny any remaining allegations.
- 22. Defendants admit that Plaintiff purports to invoke jurisdiction under 31 U.S.C. § 3732. Defendants further admit that Shiel maintained offices and conducted business in the Eastern District of New York. Defendants otherwise deny the allegations.
- 23. Defendants admit that Plaintiff purports to invoke venue under 31 U.S.C. § 3732(a). Defendants further admit that Shiel maintained offices and a laboratory in Brooklyn, New York and did business in the Eastern District of New York. Defendants deny any remaining allegations.
- 24. Defendants admit that Plaintiff purports to invoke jurisdiction under 31 U.S.C. § 3732(a). To the extent paragraph 24 attempts to state legal conclusions, no response is required. Defendants otherwise deny the allegations.

25. To the extent paragraph 25 attempts to summarize pleadings and docket entries in this case, those materials speak for themselves, and Defendants deny any allegations inconsistent therewith. To the extent paragraph 25 attempts to state legal conclusions, no response is required. Defendants deny any remaining allegations.

IV. RESPONSE TO "THE PARTIES"

- 26. Defendants admit that Plaintiff worked at Shiel for a period of time before Defendants' parent company acquired Shiel and further admit that, after the acquisition, Plaintiff was employed as a sales representative at Shiel from November 2013 until December 2017.
- 27. Defendants state that Shiel Medical Laboratory, Inc. is no longer named as a defendant in this action; accordingly, the allegations of paragraph 27 require no response.
 - 28. Admitted.
- 29. Defendants admit that Spectra Holdco, LLC, f/k/a Shiel Holdings, LLC, is a direct wholly owned subsidiary of Spectra Laboratories, Inc.
 - 30. Admitted.

V. RESPONSE TO "GOVERNING LAWS, REGULATIONS, AND CODES OF CONDUCT"

A. Response to "The Federal False Claims Act"

- 31. The allegations of paragraph 31 attempt to describe or summarize the False Claims Act and/or the False Claims Amendments Act, which speak for themselves, and Defendants deny any allegations inconsistent therewith. To the extent that the allegations attempt to state legal conclusions, no response is required. Defendants deny any remaining allegations.
- 32. The allegations of paragraph 32 attempt to describe or summarize the False Claims Act, which speaks for itself, and Defendants deny any allegations inconsistent therewith. To the extent that the allegations attempt to state legal conclusions, no response is required. Further, any

claims under the statute cited in paragraph 32 have been dismissed. Defendants deny any remaining allegations.

- 33. The allegations of paragraph 33 attempt to describe or summarize the False Claims Act, which speaks for itself, and Defendants deny any allegations inconsistent therewith. To the extent that the allegations attempt to state legal conclusions, no response is required. Further, any claims under the statute cited in paragraph 33 have been dismissed. Defendants deny any remaining allegations.
- 34. The allegations of paragraph 34 attempt to describe or summarize the False Claims Act, which speaks for itself, and Defendants deny any allegations inconsistent therewith. To the extent that the allegations attempt to state legal conclusions, no response is required. Further, any claims under the statute cited in paragraph 34 have been dismissed. Defendants deny any remaining allegations.
- 35. The allegations of paragraph 35 attempt to describe or summarize the False Claims Act, which speaks for itself, and Defendants deny any allegations inconsistent therewith. To the extent that the allegations attempt to state legal conclusions, no response is required. Further, any qui tam claims in this action have been dismissed. Defendants deny any remaining allegations.
- 36. The allegations of paragraph 36 attempt to describe or summarize the False Claims Act, which speaks for itself, and Defendants deny any allegations inconsistent therewith. To the extent that the allegations attempt to state legal conclusions, no response is required. Defendants deny any remaining allegations.
- 37. The allegations of paragraph 37 attempt to describe or summarize the False Claims Act, which speaks for itself, and Defendants deny any allegations inconsistent therewith. To the extent that the allegations attempt to state legal conclusions, no response is required. Defendants

deny any remaining allegations.

B. Response to "Federal Government-Funded Health Assistance Programs"

1. Response to "Medicare"

38. The allegations of paragraph 38 attempt to describe or summarize Medicare statutes and regulations, which speak for themselves, and Defendants deny any allegations inconsistent therewith. To the extent that the allegations attempt to state legal conclusions, no response is required. Defendants deny any remaining allegations.

2. Response to "Medicaid"

- 39. The allegations of paragraph 39 attempt to describe or summarize Medicaid statutes and regulations, which speak for themselves, and Defendants deny any allegations inconsistent therewith. To the extent that the allegations attempt to state legal conclusions, no response is required. Defendants deny any remaining allegations.
- 40. The allegations of paragraph 40 attempt to describe or summarize Medicaid statutes and regulations, which speak for themselves, and Defendants deny any allegations inconsistent therewith. To the extent that the allegations attempt to state legal conclusions, no response is required. Defendants deny any remaining allegations.
 - 3. Response to "General Provisions Applicable to Both Medicare and Medicaid"
 - a. Response to "Prohibitions Against Claims for Reimbursement Services that were Not Provided as Claimed, were Not Medically Necessary, or are Otherwise False or Fraudulent"
- 41. The allegations of paragraph 41 attempt to summarize a statute that speaks for itself, and Defendants deny any allegations inconsistent therewith. To the extent that the allegations attempt to state legal conclusions, no response is required. Defendants deny any remaining allegations.

- 42. The allegations of paragraph 42 attempt to summarize a statute that speaks for itself, and Defendants deny any allegations inconsistent therewith. To the extent that the allegations attempt to state legal conclusions, no response is required. Defendants deny any remaining allegations.
- 43. The allegations of paragraph 43 attempt to summarize a statute that speaks for itself, and Defendants deny any allegations inconsistent therewith. To the extent that the allegations attempt to state legal conclusions, no response is required. Defendants deny any remaining allegations.

VI. <u>RESPONSE TO "SPECIFIC ALLEGATIONS"</u>

A. Response to "Medicare Billing for Diagnostic Laboratory Procedures"

- 44. The allegations in paragraph 44 attempt to state legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations.
- 45. The allegations of paragraph 45 attempt to state legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations.
- 46. Defendants admit that Shiel required diagnosis codes to be received from the ordering physician or other authorized person and admit that ICD-10 (or, previously, ICD-9) codes can be used to designate a diagnosis. The remaining allegations in paragraph 46 attempt to state legal conclusions to which no response is required. Defendants deny any remaining allegations.
- 47. The allegations of paragraph 47 purport to quote from a document that speaks for itself, and Defendants deny any allegations inconsistent therewith. To the extent paragraph 47 attempts to state legal conclusions, no response is required. Defendants deny any remaining allegations.
 - 48. The allegations of paragraph 48 purport to quote from website material that speaks

for itself, and Defendants deny any allegations inconsistent therewith. Defendants deny any remaining allegations.

- 49. The allegations of paragraph 49 attempt to describe or summarize Medicare statutes and regulations, which speak for themselves, and Defendants deny any allegations inconsistent therewith. To the extent that the allegations attempt to state legal conclusions, no response is required. Defendants deny any remaining allegations.
- 50. The allegations of paragraph 50 attempt to describe or summarize Medicare statutes and regulations, which speak for themselves, and Defendants deny any allegations inconsistent therewith. To the extent that the allegations attempt to state legal conclusions, no response is required. Defendants deny any remaining allegations.
- 51. The allegations of paragraph 51 purport to quote from a document that speaks for itself, and Defendants deny any allegations inconsistent therewith. Defendants deny any remaining allegations.
- 52. To the extent paragraph 52 attempts to state legal conclusions, it requires no response. Defendants deny any remaining allegations.

B. Response to "Shiel's Fraudulent Coding and Billing Practices"

- 53. Denied.
- 54. Defendants admit that, in general, a payor may reject a clinical laboratory's reimbursement request that does not meet payor requirements, including with respect to diagnosis codes. Defendants are without knowledge or information sufficient to admit or deny the remaining allegations in paragraph 54, which does not identify any "claim" that allegedly was "rejected." Defendants deny any remaining allegations.
 - 55. Defendants admit that Shiel's billing department generated "Missing Diagnosis

Codes" or "Missing ICD9" sheets from time to time but deny that paragraph 55 fully and accurately reflects Shiel's practices. To the extent paragraph 55 purports to describe documents, they speak for themselves, and Defendants deny any allegations inconsistent therewith. Defendants deny any remaining allegations.

- 56. Defendants admit that Shiel's billing department generated "Missing Diagnosis Codes" or "Missing ICD9" sheets from time to time but deny that paragraph 56 fully and accurately reflects Shiel's practices. To the extent paragraph 56 purports to describe documents, they speak for themselves, and Defendants deny any allegations inconsistent therewith. Defendants deny any remaining allegations.
- 57. To the extent paragraph 57 purports to describe "Missing Diagnosis Codes" or "Missing ICD9" sheets, the documents speak for themselves, and Defendants deny any allegations inconsistent therewith. Defendants deny any remaining allegations.
- 58. Defendants admit that, for a period of time, Shiel's billing department generated "Missing Diagnosis Codes" or "Missing ICD9" sheets that were distributed to Shiel sales representatives for follow-up with the ordering physician or other authorized person but deny that paragraph 58 fully and accurately reflects Shiel's practices. To the extent paragraph 58 purports to describe documents, they speak for themselves, and Defendants deny any allegations inconsistent therewith. Defendants deny any remaining allegations.
- 59. Defendants admit that "Missing Diagnosis Codes" or "Missing ICD9" sheets were used from time to time in connection with collecting diagnosis codes and admit that Shiel required diagnosis codes to be received from the ordering physician or other authorized person. Defendants deny any remaining allegations.
 - 60. Defendants admit that, in general, a clinical laboratory may correct and re-submit

a reimbursement request that has previously been rejected. Defendants deny any remaining allegations.

- 61. Denied.
- 62. Denied.
- 63. Denied.
- 64. Denied.
- 65. Denied.
- 66. Denied.
- 67. Denied.
- 68. Denied.
- 69. Defendants admit that Olga Jedinak worked at Shiel and Steve Morea was a regional sales director at Shiel for a period of time. To the extent paragraph 69 purports to summarize a physician's "test orders" and internal documents, those materials speak for themselves, and Defendants deny any allegations inconsistent therewith. Any remaining allegations are denied.
- 70. Defendants lack knowledge or information sufficient to admit or deny the allegations of paragraph 70 regarding alleged interactions between Shiel employees and a physician, and therefore deny the same.
- 71. Defendants admit that Erica Ryan was an account executive at Shiel for a period of time and was assigned to follow up with certain providers regarding diagnosis codes. The remaining allegations are denied.
 - 72. Denied.
 - 73. Denied.

- 74. Defendants admit that Sal Prifitera was a Vice President at Shiel for a period of time. The remaining allegations are denied.
- 75. Defendants admit that Robin Cochrane and Doreen Mirlas worked at Shiel for a period of time. The remaining allegations are denied.
- 76. Defendants admit that James Gordon worked as a sales representative at Shiel for a period of time. Defendants further admit that Gordon worked with certain nursing home accounts. Defendants deny any remaining allegations.
- 77. To the extent paragraph 77 purports to describe "Missing Diagnosis Codes" or "Missing ICD9" sheets involving nursing homes, the documents speak for themselves, and Defendants deny any allegations inconsistent therewith. Defendants admit that Gordon was assigned to follow up with certain providers regarding diagnosis codes. Defendants deny any remaining allegations.
- 78. Defendants lack knowledge or information sufficient to admit or deny allegations related to Gordon's "concerns" or mental state and therefore deny same. Defendants deny the remaining allegations.
 - 79. Denied.
 - 80. Denied.
 - 81. Denied.
 - 82. Denied.
 - 83. Denied.
 - 84. Denied.
- 85. Defendants lack knowledge or information sufficient to admit or deny allegations regarding any statements at a sales meeting and sales representatives' state of mind, and therefore

deny same. Defendants deny any remaining allegations.

86. Defendants lack knowledge or information sufficient to admit or deny the allegations concerning Plaintiff's state of mind, and therefore deny same. Defendants deny the remaining allegations.

Response to "Sales Reps' Incentive Compensation Propelled the Coding Fraud"

- 87. Denied.
- 88. Defendants admit that sales representatives could earn commission as part of their overall compensation. Defendants also admit that sales representatives who failed to meet performance expectations could be subject to corrective action. To the extent paragraph 88 attempts to summarize internal documents, those materials speak for themselves, and Defendants deny any allegations inconsistent therewith. Defendants deny any remaining allegations.
 - 89. Denied.
- 90. To the extent paragraph 90 purports to describe internal documents, such materials speak for themselves, and Defendants deny any allegations inconsistent therewith. Defendants deny any remaining allegations.
- 91. The allegations of paragraph 91 purport to quote a portion of a document that speaks for itself, and Defendants deny any allegations inconsistent therewith and deny that paragraph 91 accurately reflects the full contents of the document. Defendants deny any remaining allegations.
- 92. The allegations of paragraph 92 purport to quote a portion of a document that speaks for itself, and Defendants deny any allegations inconsistent therewith and deny that paragraph 92 accurately reflects the full contents of the document. Defendants deny any remaining allegations.

93. The allegations of paragraph 93 purport to quote a portion of a document that speaks for itself, and Defendants deny any allegations inconsistent therewith and deny that paragraph 93 accurately reflects the full contents of the document. Defendants deny any remaining allegations.

Response to "Kickbacks"

- 94. Denied.
- 95. Denied.
- 96. Denied.
- 97. Denied.
- 98. Denied.
- 99. Denied.
- 100. Denied.
- 101. Denied.
- 102. Defendants admit that they implemented a gifts, meals, and entertainment policy consistent with applicable law and conducted compliance training on same. Defendants lack knowledge or information sufficient to admit or deny the allegations related to verbal conversations and therefore deny same. Defendants deny any remaining allegations.

VIII. RESPONSE TO "DEFENDANTS UNLAWFULLY RETALIATED AGAINST RELATOR, TERMINATED RELATOR'S EMPLOYMENT, <u>AND PREVENTED HIS RE-EMPLOYMENT"</u>

A. Response to "Realtor Blows the Whistle on Defendants' Fraud"

- 103. Denied.
- 104. Defendants lack knowledge or information sufficient to admit or deny allegations regarding Plaintiff's claimed oral statements, and therefore deny same. Defendants admit there

were concerns about Plaintiff's sales performance. The remaining allegations are denied.

- 105. Defendants admit that on or about August 15, 2016, Plaintiff had a conversation with Jim Murphy. Defendants lack knowledge or information sufficient to admit or deny the remaining allegations and therefore deny same. Defendants otherwise deny the allegations except as expressly admitted.
- 106. Defendants deny the allegations in the first sentence of paragraph 106. Defendants lack knowledge or information sufficient to admit or deny the allegations concerning any agreements made about a "followup meeting," and therefore deny same. Defendants deny any remaining allegations.
- 107. Defendants lack knowledge or information sufficient to admit or deny the allegations in the first sentence of paragraph 107, and therefore deny same. Defendants admit that a written warning was issued to Plaintiff in August 2016 but lack knowledge or information regarding whether this "was a first for" Plaintiff. To the extent paragraph 107 purports to quote or paraphrase internal documents that speak for themselves, Defendants deny any allegations inconsistent therewith. Defendants deny any remaining allegations.
- 108. The allegations of paragraph 108 purport to summarize documents that speak for themselves, and Defendants deny any allegations inconsistent therewith. Defendants deny any remaining allegations.
- 109. Defendants admit that Plaintiff sent an email to Peter Connelly on September 6, 2016, and admit that Connelly served as Ethics and Compliance Officer, Laboratory Services. To the extent paragraph 109 purports to describe the email, it speaks for itself, and Defendants deny any allegations inconsistent therewith. Any remaining allegations are denied.
 - 110. The allegations of paragraph 110 purport to quote and summarize a document that

speaks for itself, and Defendants deny any allegations inconsistent therewith. Defendants deny any remaining allegations.

- 111. The allegations of paragraph 111 purport to quote and summarize a document that speaks for itself, and Defendants deny any allegations inconsistent therewith. Defendants deny any remaining allegations.
- 112. The allegations of paragraph 112 purport to quote and summarize a document that speaks for itself, and Defendants deny any allegations inconsistent therewith. Defendants deny any remaining allegations.
- 113. Defendants admit that Connelly responded to Plaintiff's September 6, 2016 email on September 9, 2016. Defendants further admit that Plaintiff was interviewed by in-house and outside counsel on or about September 29, 2016. The remaining allegations purport to quote or summarize documents that speak for themselves, and Defendants deny any allegations inconsistent therewith. Defendants deny any remaining allegations.

B. Response to "Defendants Retaliate Against Relator for his Whistleblowing"

- 114. Denied.
- 115. Denied.
- 116. Defendants admit that the Jewish Home of Rockleigh is a nursing home in New Jersey that was a Shiel account for a period of time in 2016-2017. The remaining allegations are denied.
- 117. Defendants admit that Catherine Winburn worked as a Director of Sales at Shiel and was Plaintiff's supervisor in 2016. Defendants state that, to the extent paragraph 117 attempts to describe any internal documents, they speak for themselves, and Defendants deny any allegations inconsistent therewith. To the extent paragraph 117 attempts to describe alleged oral

communications, Defendants lack knowledge or information sufficient to admit or deny the allegations, and therefore deny same. Any remaining allegations are denied.

- 118. Defendants state that, to the extent paragraph 118 attempts to describe any internal documents, they speak for themselves, and Defendants deny any allegations inconsistent therewith. To the extent paragraph 118 attempts to describe alleged oral communications, Defendants lack knowledge or information sufficient to admit or deny the allegations, and therefore deny same. Any remaining allegations are denied.
- 119. Defendants state that, to the extent paragraph 119 attempts to describe any internal documents, they speak for themselves, and Defendants deny any allegations inconsistent therewith. To the extent paragraph 119 attempts to describe alleged oral communications, Defendants lack knowledge or information sufficient to admit or deny the allegations, and therefore deny same. Any remaining allegations are denied.
- 120. Defendants lack knowledge or information sufficient to admit or deny the allegations of paragraph 120, and therefore deny same.
 - 121. Denied.
 - 122. Denied.
- 123. Defendants admit that Manhattan Physicians Laboratories, LLC, is based in New York City. To the extent paragraph 123 attempts to describe any internal documents, they speak for themselves, and Defendants deny any allegations inconsistent therewith. Defendants lack knowledge or information regarding all of Plaintiff's alleged interactions with physicians and other Shiel employees and therefore deny those allegations. Any remaining allegations are denied.
- 124. Defendants lack knowledge or information regarding Plaintiff's alleged interactions with Prifitera and therefore deny those allegations. The remaining allegations are

denied.

- 125. Defendants state that, to the extent paragraph 125 attempts to describe any internal documents, they speak for themselves, and Defendants deny any allegations inconsistent therewith. To the extent paragraph 125 attempts to describe alleged oral communications, Defendants lack knowledge or information sufficient to admit or deny the allegations, and therefore deny same. Any remaining allegations are denied..
- 126. Defendants state that, to the extent paragraph 126 attempts to describe any internal documents, they speak for themselves, and Defendants deny any allegations inconsistent therewith. To the extent paragraph 126 attempts to describe alleged oral communications, Defendants lack knowledge or information sufficient to admit or deny the allegations, and therefore deny same. Any remaining allegations are denied.
- 127. Paragraph 127 attempts to describe an internal document that speaks for itself, and Defendants deny any allegations inconsistent therewith. Any remaining allegations are denied.
- 128. Paragraph 128 attempts to describe an internal document that speaks for itself, and Defendants deny any allegations inconsistent therewith. Any remaining allegations are denied.

C. Response to "The Government Investigates Shiel and Retaliation Against Relator Increases"

129. Defendants admit that Hogan Lovells was involved in an internal investigation at Shiel in 2016. To the extent that admitting or denying other allegations in paragraph 129 would require Defendants to divulge information protected by the attorney-client privilege, Defendants stand on the privilege. To the extent paragraph 129 attempts to describe any internal documents, they speak for themselves, and Defendants deny any allegations inconsistent therewith. To the extent paragraph 129 attempts to describe alleged oral communications, Defendants lack knowledge or information sufficient to admit or deny the allegations, and therefore deny same.

Any remaining allegations are denied.

- 130. To the extent the allegations of paragraph 130 purport to summarize a document that speaks for itself, Defendants deny any allegations inconsistent therewith. To the extent that admitting or denying other allegations in paragraph 130 would require Defendants to divulge information protected by the attorney-client privilege, Defendants stand on the privilege. Defendants deny any remaining allegations except as expressly admitted.
- 131. To the extent paragraph 131 attempts to describe or summarize any internal documents, they speak for themselves, and Defendants deny any allegations inconsistent therewith. To the extent paragraph 131 attempts to describe alleged oral communications including hearsay, Defendants lack knowledge or information sufficient to admit or deny the allegations, and therefore deny same. Any remaining allegations are denied.
- 132. To the extent paragraph 132 attempts to describe alleged oral communications including hearsay, Defendants lack knowledge or information sufficient to admit or deny the allegations, and therefore deny same. Any remaining allegations are denied.
- 133. To the extent paragraph 133 attempts to describe any internal documents, they speak for themselves, and Defendants deny any allegations inconsistent therewith. To the extent paragraph 133 attempts to describe alleged oral communications, Defendants lack knowledge or information sufficient to admit or deny the allegations, and therefore deny same. Any remaining allegations are denied.
- 134. Paragraph 134 attempts to describe internal documents that speak for themselves, and Defendants deny any allegations inconsistent therewith. To the extent paragraph 134 makes allegations about Plaintiff's state of mind, Defendants lack knowledge or information sufficient to admit or deny the allegations, and therefore deny same. Any remaining allegations are denied.

- 135. Defendants admit that on or about March 29, 2017, Plaintiff had a performance review. Defendants lack knowledge or information sufficient to form a belief about the truth of Plaintiff's state of mind during the review and who was in attendance and therefore deny same. Defendants deny any remaining allegations.
- 136. The allegations of paragraph 136 purport to summarize internal documents that speak for themselves, and Defendants deny any allegations inconsistent therewith. Defendants deny any remaining allegations.
- 137. To the extent the allegations of paragraph 137 purport to summarize documents that speak for themselves, Defendants deny any allegations inconsistent therewith. Defendants admit that Plaintiff refused to sign the performance review. Defendants lack knowledge or information sufficient to admit or deny the remaining allegations, and therefore deny them. Defendants deny any remaining allegations.
- 138. Defendants lack knowledge or information sufficient to admit or deny the allegations of paragraph 138 and therefore deny same.
- 139. To the extent paragraph 139 attempts to describe any internal documents, they speak for themselves, and Defendants deny any allegations inconsistent therewith. To the extent paragraph 139 attempts to describe alleged oral communications, Defendants lack knowledge or information sufficient to admit or deny the allegations, and therefore deny same. Defendants deny any remaining allegations.
- 140. Paragraph 140 has been stricken by the Court and requires no response. *See* ECF 44 at 21.
- 141. The allegations of paragraph 141 purport to describe and quote a document that speaks for itself, and Defendants deny any allegations inconsistent therewith. Defendants deny any

remaining allegations.

D. Response to "Fresenius sells Shiel to Quest, and Defendants Further Retaliate Against Relator"

- 142. Defendants admit that the sale of Shiel to Quest Diagnostics, Inc. ("Quest") was publicly announced in late September 2017. Any remaining allegations are denied.
- 143. Defendants admit that, in or around September 2017, their parent company entered an asset purchase agreement with Quest providing for Quest to purchase certain assets from Shiel which comprised substantially all of the business of Shiel. Any remaining allegations are denied.
- 144. Defendants admit that, after the sale of Shiel to Quest was announced, Shiel employees including Plaintiff were informed that their employment with Shiel would be terminated effective December 31, 2017. Defendants lack knowledge or information sufficient to admit or deny the contents of any conversation between Plaintiff and any Quest employee, and therefore deny same. Defendants deny any remaining allegations.
- 145. Defendants lack knowledge or information sufficient to admit or deny the allegations in paragraph 145, and therefore deny same.
- 146. Defendants lack knowledge or information sufficient to admit or deny the allegations in paragraph 146, and therefore deny same.
- 147. Defendants admit that Plaintiff was paid commissions. To the extent paragraph 147 attempts to describe any internal documents, they speak for themselves, and Defendants deny any allegations inconsistent therewith. To the extent paragraph 147 attempts to describe alleged oral communications, Defendants lack knowledge or information sufficient to admit or deny the allegations, and therefore deny same. Defendants deny any remaining allegations.
 - 148. Denied.
 - 149. Defendants lack knowledge or information sufficient to admit or deny the

allegations of paragraph 149, and therefore deny same.

IX. RESPONSE TO "CLAIMS FOR RELIEF"

RESPONSE TO "FIRST CAUSE OF ACTION"

("False Claims Act: Retaliation") (31 U.S.C. § 3730(h))

150. Defendants restate and incorporate herein by reference the responses contained in all other paragraphs of this Answer as if fully set forth herein.

151. Denied.

152. Denied.

X. RESPONSE TO "DEMANDS FOR RELIEF"

Defendants deny the allegations contained in Plaintiff's "Demands for Relief" and deny that Plaintiff is entitled to any relief.

ADDITIONAL AND AFFIRMATIVE DEFENSES

As affirmative and additional defenses to Plaintiff's Third Amended Complaint, and without assuming any burden of pleading or proof that otherwise would rest on Plaintiff, Defendants allege the following:

- Defendants deny each and every allegation in the Third Amended Complaint not expressly admitted.
- 2. The Third Amended Complaint fails to state a claim upon which relief may be granted.
- 3. Plaintiff's claims are time barred to the extent that they were not filed within the applicable statute of limitation period(s).
- 4. All actions taken by Defendants were for legitimate, non-retaliatory business reasons.

- 5. Plaintiff's claims are barred because Defendants, at all times relevant to this lawsuit, complied with all applicable laws and regulations and acted in good faith.
- 6. To the extent that any recovery by Plaintiff may be completely or partially barred due to after-acquired evidence, any recovery which Plaintiff might otherwise be entitled must be appropriately offset.
- 7. To the extent that any recovery by Plaintiff may be completely or partially barred due to Plaintiff's participation in the conduct of which he complains and delay in reporting the conduct of which he complains to the United States, any recovery to which Plaintiff might otherwise be entitled must be appropriately offset.
- 8. Plaintiff's claims are barred, in whole or in part, but the equitable doctrines of waiver, estoppel, laches and/or unclean hands.
- 9. Plaintiff's claims are barred, and any recovery should be diminished, reduced, or offset, due to the comparative and/or contributory negligence, fault, responsibility, or causation of others.
- 10. Any alleged adverse action Plaintiff claims to have experienced was not caused by, and would have occurred regardless of, Plaintiff's alleged protected activity.
- 11. Defendants reserve the right to amend this Answer, including the right to add additional affirmative defenses, as may become necessary or apparent during the course of discovery in this case.
 - 12. Defendants demand a trial by jury.

Wherefore, for the foregoing reasons, Defendants Spectra Holdco, LLC f/k/a Shiel Holdings LLC and Spectra Laboratories, Inc., respectfully request that the Court enter judgment

on their behalf on Relator's Third Amended Complaint, including an award of fees and costs of suit, and such other relief as the Court deems just and appropriate.

Dated: February 20, 2024 Respectfully submitted,

/s/ James F. Bennett

Dowd Bennett LLP

James F. Bennett (admitted *pro hac vice*)

jbennett@dowdbennett.com

Megan S. Heinsz (admitted *pro hac vice*)

mheinsz@dowdbennett.com

Hannah F. Preston (admitted pro hac vice)

hpreston@dowdbennett.com

7676 Forsyth Boulevard, Suite 1900

St. Louis, Missouri 63105

Tel: (314) 889-7300

Fax: (314) 863-2111

Vinson & Elkins

James G. McGovern NYS REG.2533693

jmcgovern@velaw.com

1114 Avenue of the Americas

32nd Floor

New York, New York 10036

Tel: (212) 237-0000

Fax: (212) 237-01000

Counsel for Defendants, Spectra Holdco, LLC f/k/a Shiel Holdings LLC and Spectra Laboratories, Inc.

CERTIFICATE OF SERVICE

I hereby certify that on this 20th day of February, 2024, the foregoing document filed through the CM/ECF system will be sent electronically to the registered participants as identified on the NEF (NEF).

/s/ James F. Bennett
Counsel for Defendants